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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/306,591	08/31/99	NEEDLEMAN	P MUN-193.00CN

HM22/0213

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EXAMINER	
ANDRES, J	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-473-000/44602

1- File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/386,591	NEEDLEMAN ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-7,12,13 and 22-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,12,13 and 22-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

2. Applicant's amendment and Declaration under 37 C.F.R. 1.131 filed November 27, 2000, in paper no. 6 are acknowledged. Claims 3-7, 12, 13, and 22-39 are pending in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

3. The rejection of claims 3, 6, 7, 22, 23, 26-31, and 33-36 as being unpatentable over Rittershaus and Thomas in view of Donnelly et al. and further in view of Francis and Clarke is withdrawn in response to applicant's Declaration under 37 C.F.R. 1.131. The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as lacking antecedent basis for "said antigenic carrier" is withdrawn in response to applicant's arguments. The rejection of claim 12 as lacking antecedent basis for "encoded fusion protein" is withdrawn in response to applicant's amendment. The rejection of claim 3 is withdrawn in response to applicant's correction.

Claim Rejections Maintained/New Grounds of Rejection

Claim Rejections - 35 USC § 103

4. The rejection of claims 3, 6, 7, 26, 29, 30, and 34-36 as being unpatentable over Thomas et al. in view of Francis and Clarke, the rejection of claims 4, 5, and 37-39 as being unpatentable over Thomas et al. in view of Francis and Clarke and further in view of Donnelly et al., and the rejection of claims 12, 13, and 32 as being unpatentable over Thomas et al. in view of Brown et

al. are maintained. Applicant has provided a Declaration under 37 C.F.R. 1.131 to overcome these references. However, applicant's Declaration did not reduce the claimed invention to practice prior to the cited art. Applicant's Declaration teaches the use of peptides as antigens. However, the responses, results, and mechanisms of action seen with peptide antigens are not predictive of similar outcomes from administration of a DNA vaccine. Eck and Wilson, in the 9th edition of Goodman and Gilman's The Pharmacological Basis of Therapeutics (1996, pages 77-101), teaches that the considerations necessary for a successful DNA vaccine are different from what is required for a peptide vaccine. Factors to be considered include: distribution of the DNA vector, the fraction of the vector taken up by the target cell population, the intracellular trafficking, rate of degradation of DNA, mRNA stability, and compartmentalization and secretion of the expressed protein (p. 82). Successful administration of a peptide antigen is predictive of none of these factors: the physical and thus pharmacokinetic characteristics of the administered molecules, as well as the processes involved in the production of an antigenic response, are entirely different. Thus applicant's declaration showing successful use of peptide antigens is not predictive of a DNA vaccine. Thomas et al., however, does teach a CETP DNA vaccine, as set forth in the previous office action. Francis and Clarke, Donnelly et al., and Brown et al. teach modifications as set forth in the previous office action. Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to combine the teachings of Thomas et al. with those of Francis and Clarke, Donnelly et al., or Brown et al. to arrive at the claimed invention. One of ordinary skill would have been motivated to do so because Thomas et al. teaches CETP DNA vaccines and Francis and Clarke, Donnelly et al., and Brown et al. each teach modifications that increase the utility or effectiveness of such vaccines.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 22, 25, 27, 28, 31, and 33 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman,* (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Each of these claims is drawn to vaccines and methods using specific peptide sequences. No guidance is set forth in the specification to indicate to one of skill that DNA vaccines encoding those particular sequences could be successfully used to generate an antigenic response. Further, the prior art does not provide compensatory teachings: the art teaches peptide vaccines incorporating these particular sequences, not DNA vaccines (Rittershaus and Thomas, cited in the previous office action). Eck and Wilson, cited above, teaches that "the delivery of exogenous DNA and its processing by target cells require the introduction of new pharmacokinetic paradigms beyond those that describe the conventional medicines in use today" (p. 81). The success of such an approach is thus not predictable, as discussed above.

Specifically, it is not predictable that any particular peptide would be produced in sufficient amounts, processed, and secreted (p. 82). Thus the success of a peptide vaccine is not predictive of the success of a DNA vaccine: they are different chemical entities with different mechanisms of action, and different considerations are required. Gene therapy is still "in the infant stages of development" (Eck and Wilson, p. 99); thus specific guidance is needed for the skilled artisan to use the invention. In the instant specification, applicant has provided no such guidance to indicate that the particular peptides selected would function in a DNA vaccine. Without further direction, therefore, it would undue experimentation for one of skill in the art to make and use such DNA vaccines.

7. The rejection of claim 28 as being improperly dependent, made of record in the previous office action, is maintained until such time as the claims are renumbered.

Double Patenting

8. The rejection of claims 3-7, 12, 13, and 22-39 under the provision of obviousness-type double patenting, made of record in the previous office action, is maintained until such time as a terminal disclaimer is filed.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
February 12, 2001

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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